

IN THE CLAIMS

1. (Currently amended) A stable, liquid pharmaceutical formulation of human parathyroid hormone at a concentration of 0.3 mg/ml to 10 mg/ml, comprising (i) human parathyroid hormone, (ii) a pharmaceutically acceptable buffer of pH 4 to 6, (iii) NaCl, (iv) mannitol, (v) a preservative, and (vi) water. ~~at a concentration of 0.3 mg/ml to 10 mg/ml; a pharmaceutically acceptable buffer having a pH from 4 to 6, and at least one tonicity modifier that is NaCl.~~

2. (Currently amended) The pharmaceutical formulation according to claim 1, wherein the ~~said~~ human parathyroid hormone is human recombinant parathyroid hormone.

3. (Currently amended) The pharmaceutical formulation according to claim 1, wherein the ~~said~~ human parathyroid hormone is a full-length parathyroid hormone.

4. (Currently amended) The pharmaceutical formulation according to claim 1, wherein the concentration of the ~~said~~ human parathyroid hormone is from 0.3 mg/ml to 5 mg/ml.

5. (Currently amended) The pharmaceutical formulation according to claim 4, wherein the concentration of the ~~said~~ human parathyroid hormone is from 1 mg/ml to 3 mg/ml.

6. (Currently amended) The pharmaceutical formulation according to claim 1, wherein the ~~said~~ pharmaceutically acceptable buffer is a citrate buffer at a concentration from 5 to 20 mM.

7. (Currently amended) The pharmaceutical formulation according to claim 1, wherein the ~~said~~ pharmaceutically acceptable buffer has a pH between 5 and 6.

8. (Cancel) The formulation according to claim 1, further comprising a second tonicity modifier that is mannitol.

9. (Currently amended) A stable, liquid pharmaceutical formulation of human parathyroid hormone, comprising 1 to 3 mg/ml parathyroid hormone, 2 to 5 mg/ml NaCl, 20 to 50 mg/ml mannitol, a preservative, and 5 to 10 mM citrate buffer at a pH between 4 and 6.

10. (Cancel) The formulation according to claim 1 in liquid form.

11. (Cancel) The formulation according to claim 1 in lyophilized form.

12. (Currently amended) A process for the preparation of a pharmaceutical formulation according to claim 1, comprising dissolving human parathyroid hormone, to a concentration from 0.3 to 10 mg/ml, sodium chloride, and mannitol ~~and at least one tonicity modifier~~, in a pharmaceutically acceptable buffer having a pH between 4 and 6.

13. (Previously cancelled)

14. (Previously cancelled)

15. (Previously cancelled)

16. (Previously cancelled)

17. (Previously amended) A method for treating a bone related disorder or reducing or inhibiting bone loss associated with a bone related disorder, comprising administering to a mammal, including man, in need of such treatment or inhibition, an effective amount of the formulation of claim 1.

18. (Previously amended) The method according to claim 17, wherein the bone related disorder is osteoporosis.

19. (Cancelled) The pharmaceutical formulation of claim 9, further comprising a preservative.

20. (Previously added) The pharmaceutical formulation of claim 9 ~~19~~, wherein the preservative is benzyl alcohol, m-cresol or EDTA.

21. (Previously added) The pharmaceutical formulation of claim 9, wherein the parathyroid hormone is human recombinant parathyroid hormone.

22. (Previously added) The pharmaceutical formulation of claim 9, wherein the parathyroid hormone is human full-length parathyroid hormone.

23. (Previously added) The pharmaceutical formulation of claim 9, wherein the pH of the citrate buffer is between 5 and 6.

24. (Currently amended) A stable, liquid pharmaceutical formulation comprising 1 to 3 mg/ml parathyroid hormone, 2 to 5 mg/ml NaCl, 20 to 50 mg/ml mannitol, 5 to 10 mM citrate buffer at a pH between 4 and 6, and a preservative.

25. (Previously added) The pharmaceutical formulation of claim 24, wherein the preservative is benzyl alcohol, m-cresol or EDTA.

26. (Previously added) The pharmaceutical formulation of claim 24, wherein the parathyroid hormone is human recombinant parathyroid hormone.

27. (Previously added) The pharmaceutical formulation of claim 24, wherein the parathyroid hormone is human full-length parathyroid hormone.

28. (Previously added) The pharmaceutical formulation of claim 24, wherein the pH of the citrate buffer is between 5 and 6.

29. (withdrawn by the Examiner in Office Action of 03.24.03)

30. (withdrawn by the Examiner in Office Action of 03.24.03)
31. (Previously added) The pharmaceutical formulation~~method~~ of claim 1, wherein the concentration of the NaCl is between 2 to 5 mg/ml.
32. (Previously added) The pharmaceutical formulation of claim 1, wherein the parathyroid hormone is human recombinant parathyroid hormone (1-84).
33. (Previously added) The pharmaceutical formulation of claim 9, wherein the parathyroid hormone is human recombinant parathyroid hormone (1-84).
34. (Previously added) The pharmaceutical formulation of claim 24, wherein the parathyroid hormone is human recombinant parathyroid hormone (1-84).
35. (Previously added) A method for treating a bone related disorder or reducing or inhibiting bone loss associated with a bone related disorder, comprising administering to a mammal, including man, in need of such treatment or inhibition, an effective amount of the formulation of claim 9.
36. (Previously added) The method according to claim 35, wherein the bone related disorder is osteoporosis.